



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,856	06/27/2003	Benjamin J. Bottcher	BSCU-011/01US223C1	8238

22903 7590 06/16/2005

COOLEY GODWARD LLP
ATTN: PATENT GROUP
11951 FREEDOM DRIVE, SUITE 1700
ONE FREEDOM SQUARE- RESTON TOWN CENTER
RESTON, VA 20190-5061

EXAMINER

SNOW, BRUCE EDWARD

ART UNIT	PAPER NUMBER
----------	--------------

3738

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/608,856

Applicant(s)

BOTTCHER ET AL.

Examiner

Bruce E Snow

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 42-46 and 48-51 is/are allowed.
- 6) ☒ Claim(s) 47, 52-55, 57-66 is/are rejected.
- 7) ☒ Claim(s) 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/24/03 (non US).
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's amendments and arguments filed 3/21/05 have been fully considered the Examiner's position is stated below.

Allowable Subject Matter

Claims 42-46, 48, and 51 are allowable upon the clarification of "origin of the coil" and "end of the coil" in the specification/claim and overcoming the claim objection. Similar for claim 56.

Claim Objections

Claims 42, 52 (similar for claim 60) are objected to because of the following informalities: As discussed in the interview, change "coaxial with the axis" to "coaxial with said axis" for clarification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 47 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The second material being softer is new matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 60-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 60, "the medial portion being substantially orthogonal to the substantially planar coil of the first retention portion" is ambiguous. Is the axis perpendicular (orthogonal) to the plane of the planar coil?

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claim 42, "origin of the coil" and "end of the coil" are not defined and not supported in the specification. Which one connects to the third section?

Regarding claim 60, "the medial portion being substantially orthogonal to the substantially planar coil of the first retention portion" is not found in the specification.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 52-55, 57-63, and 65-66 are rejected under 35 U.S.C. 102(b) as being anticipated by "Ureteral Stints and Ureteral Catheters (applicant submitted C37).

Referring to all figures, including figure 2, the catalog teaches a medical stent comprising:

an elongate member having a first retention portion (left end), a second retention portion (right end), and a medial portion disposed between the first retention portion and the second retention portion,

the first retention portion configured to be placed in a bladder of a patient and including a substantially planar coil, the second retention portion being configured to be placed in a kidney of the patient, the medial portion defining an axis, the axis defined by the medial portion being substantially orthogonal to the substantially planar coil of the first retention portion. The coil is interpreted to be simply a portion of the retention portion, such as the first turn, which is substantially planar.

The first material and second material inherently can not be the same material. This limitation is not claiming they are a different type of material.

Regarding at least claims 54-55, the catalog teaches various durometers which would meet the claimed ranges.

Claims 60, 62-66 are rejected under 35 U.S.C. 102(b) as being anticipated by Balbierz et al (5,964,744).

Referring to all figures, including figure 12A, Balbierz et al teaches a medical stent comprising:

an elongate member having a first retention portion 804, a second retention portion 804, and a medial portion 801 disposed between the first retention portion and the second retention portion,

the first retention portion configured to be placed in a bladder of a patient and including a substantially planar coil, the second retention portion being configured to be placed in a kidney of the patient, the medial portion defining an axis, the axis defined by the medial portion being substantially orthogonal to the axis of substantially planar coil of the first retention portion.

Regarding claim 62, (Note U.S. Patent 5,599,291, which is incorporated by reference teaches the retention means can be any desired shape which will provide adequate anchoring including a helical curl which fulfills the claimed configuration; see at least column 5, lines 21 et seq.);

a second section comprising a second material, defining a lumen, and comprising a second coil 24 completing at least one revolution; and

a third section defining a lumen and located between the first and second sections and adjacent the origin of the first coil, at least a portion of the third section comprising a co-extrusion of the first and second materials.

Regarding the first and second materials and their co-extrusion, Balbierz et al teaches the entire stent can be formed of a substrate layer and a coating which can be co-extruded therewith. See at least column 11, lines 4 et seq. The coating can be interpreted as the first material and the substrate layer can be interpreted as the second

material, or vice versa. Additionally, the different first and second material can be interpreted as being the same material.

Regarding at least claims , see 12:1 et seq. of 5,599,291.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone

Art Unit: 3738

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bes



BRUCE SNOW
PRIMARY EXAMINER